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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,955

04/15/2004

Kenneth T. Heruth

1023-362US01

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28863

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07/20/2006

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/825,955

Applicant(s)

HERUTH ET AL.

Examiner

Jeffrey G. Hoekstra

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15, 17-42 and 44-68 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10, 12-15, 17-20, 28-42 and 44-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9, 11 and 17-27 is/are rejected.
- 7) ☒ Claim(s) 11 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 06/30/2006, amended claims 1, 26, 28, 42, 57, and 65 and canceled claims 16 and 43 are acknowledged.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group I in the reply filed on 06/30/2006 is acknowledged. The traversal is on the ground(s) that no serious burden exists because many of the dependent claims are substantially similar and that materially different processes have not been provided. This is not found persuasive because Groups I-III differ widely in scope and Groups II and III can be used to practice materially different processes such as periodically determining, monitoring, tracking, and displaying the three-dimensional spatial orientation of a patient via the plurality of orthogonally aligned accelerometers for use in rehabilitation analysis in a post-surgical biomechanic-correction procedure, tracking and studying the tic biomechanical motion of patients with Tourette's syndrome, and/or monitoring trembling associated with Parkinson's disease.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 28-42 and 44-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

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generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/30/2006.

4. Applicant's election without traverse of Species B in the reply filed on 06/30/2006 is acknowledged. Claims 7, 10, 12-20, 34, 37, and 39-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/30/2006.

5. The examiner notes applicant indicated that claims 17-20 were drawn to Species B and therefore ready for examination however claims 17-20 are withdrawn as being dependent upon withdrawn claims.

6. Applicant's election without traverse of Species BB in the reply filed on 06/30/2006 is acknowledged. Claim 63 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/30/2006.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

8. The information disclosure statement(s) (IDS) submitted on 04/07/2005, 09/26/2005, 09/29/2005, 03/21/2006, and 06/16/2006 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

9. The examiner notes the following: Non-Patent Literature submission cited Michael T. Smith et al., "How do sleep disturbance and chronic pain inter-related?", Sleep Medicines Reviews, YSMRV 286-19/6/2003 was of poor quality and illegible in areas and thus not considered; resubmission is encouraged.

***Claim Objections***

10. Claim 11 is objected to because of the following informalities: claim 11 positively recites the limitation "the sleep quality metric" in lines 1-2, there appears to be insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

11. Claim 22 is objected to because of the following informalities: claim 22 positively recites the limitation "the medical device" in line 1, there appears to be insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-6, 8, 9, 11, and 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al (US 6,351,672 B1). Park et al discloses a method, comprising:

- monitoring a plurality of physiological parameters of a patient via a medical device (10), wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity (column 3 lines 6-25 and lines column 5 lines 23-47);
- determining when the patient is attempting to sleep (Figure 5 and column 7 lines 24-31);
- determining values of at least one metric (the transfer function as best seen in Figure 2) that is indicative of sleep quality based on at least one of the physiological parameters, a determination that the patient is attempting to sleep, on the determined activity level; and
- periodically determining an activity level of the patient based on at least one of the physiological parameters and a determination that the patient is not attempting to sleep (column 7 lines 10-24 and 31-61).

14. For claim 2, Park et al discloses a method wherein determining when the patient is attempting to sleep comprises receiving an indication (the sensed activity levels via sensor 68) from the patient that the patient is attempting to sleep (column 7 lines 24-31).

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15. For claims 3 and 4, Park et al discloses a method wherein monitoring a plurality of physiological parameters comprising monitoring (a) at least one signal that indicates posture of the patient and determining when the patient is attempting to sleep comprises determining when the patient is recumbent (column 7 line 10 – column 8 lines 31) and (b) a signal from each of a plurality of orthogonally aligned accelerometers, and determining when the patient is recumbent comprises determining when the patient is recumbent based on a DC component of each of the signals (column 2 lines 51-65 and column 3 lines 6-27).

16. For claims 5 and 6, Park et al discloses a method wherein determining when the patient is attempting to sleep comprises: (a) determining when the patient is attempting to sleep based on a physical activity level of the patient (column 7 lines 24-31) and (b) comparing the activity level to an activity level threshold and comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold (column 3 lines 33 – 39 and column 6 line 54 – column 7 line 9).

17. For claims 8 and 9, Park et al discloses a method wherein monitoring a plurality of physiological parameters comprises monitoring posture and blood oxygen saturation (column 3 lines 6-28).

18. For claim 11, Park et al discloses a method wherein the metric indicative of sleep quality comprises sleep latency, and determining values of the sleep quality metric comprises: identifying a first time when the patient is attempting to fall asleep; identifying a second time when the patient falls asleep based on at least one of the

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physiological parameters; and determining an amount of time between the first and second times (column 3 lines 33-39 and column 7 lines 10-19).

19. For claims 21-23, Park et al discloses a method wherein (a) periodically determining an activity level comprises periodically determining a number of activity counts (column 6 line 65 – column 7 line 19); (b) a medical device delivers a therapy (the pacing signals delivered by the A-pulse generator 22 and the V-pulse generator 24) to the patient according to a plurality of therapy parameter sets, the method further comprising: associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set; for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set as best seen in Figures 2 and 5; and (c) presenting a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values (column 6 line 65 – column 7 line 19).

20. For claim 25, Park et al discloses a method wherein a medical device comprises an implantable medical device (10).

***Claim Rejections - 35 USC § 103***

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of Cho et al (US 6,964,641 B2). Park et al discloses the claimed methods of using an implantable medical device including an implantable neurostimulator (10) except for implanting and/or utilizing a drug pump. Cho et al teaches a method of using an implantable medical device (10) with a drug pump (column 4 lines 46-59, column 9 lines 22-30, and column 10 lines 12-17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of using an implantable medical device as taught by Park et al, with the drug pump of Cho et al for the purpose of configuring an implantable medical device responsive to patient sleeping and posture so as to increase the efficacy of the device to respond to a patient's physical activity levels.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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